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Review Article

Ensuring effective and sustainable radionuclide delivery and its impact on the development of nuclear medicine in the developing world with special reference to Nigeria

ABSTRACT

Recent activities of Boko Haram, a local extremist group in Nigeria, raise concerns about a nuclear terrorist attack. Whereas nuclear medicine (NM) relies on the timely delivery of radioactive sources, a robust security structure that assures public safety is the backbone for its beneficial use. NM radionuclides have short half-lives and carry an insignificant risk for acts of terrorism. Yet, their importation and delivery in Nigeria receive undue scrutiny in a bid to implement a strict nuclear security regime. These actions prevent timely delivery of radionuclides with direct consequences on quality and economic viability of nuclear medicine. There have been no accounts of terrorist acts accomplished with NM radionuclides. Thus, it is important the NM community question the current approach that has contributed to the loss of NM services in Nigeria and proposes a more logical strategy for securing their supply. We also highlight the need for developing local pragmatic solutions when implementing global recommendations in developing countries.

Keywords: Development, nuclear medicine, nuclear safety

INTRODUCTION

Nuclear security encompasses the prevention, detection of and response to malicious acts involving nuclear and other radioactive material and/or their facilities.[1] The International Atomic Energy Agency (IAEA) promotes the peaceful use of atoms and guides member states on managing risks from radioactive sources.[2] Adequately credentialed professionals are recognized by National Laws to receive and possess radioactive sources based on recognized technical and administrative capability.[3]

BRIEF OVERVIEW OF RADIOACTIVITY AND NUCLEAR MEDICINE

An unstable radioactive atom releases nuclear energy to transform into a more stable one. This process is called radioactive decay.[4] Where a longer-lived radioactive nucleus decays into a shorter-lived radioactive product, a parent-daughter relationship exists between them due to physical differences in chemistry.[5] Excluding a few exceptions, the radioactivity of an atom does not affect its chemical behavior.[6] This is exploited to incorporate trace amounts of radioactive atoms into biologic systems.[7] Once attained, the radioactive atom may be used to study organ functions.[8-10] These radioactive atoms are also called radionuclides. Nuclear medicine (NM) is a field of radiation medicine that exploits the different modes of nuclear emission for imaging and/or therapy. Whereas special

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T. Akintunde Orunmuyi[1,2], M. Mike Sathekge[3], R. John Buscombe[4]

[1]Department of Radiation Oncology, College of Medicine, University of Ibadan, [2]Nuclear Medicine Centre, University College Hospital, Ibadan, Nigeria, [3]Department of Nuclear Medicine, Steve Biko Academic Hospital, Pretoria, South Africa, [4]Department of Nuclear Medicine, Cambridge University Hospitals, Cambridge, UK

Address for correspondence: Dr. M. Mike Sathekge, Steve Biko Academic Hospital, Pretoria, South Africa. E-mail: mike.sathekge@up.ac.za

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instruments like gamma cameras provide spatial information on the distribution of physiologic functions such as tumor activity, receptor concentrations, and blood flow, therapy is achieved by using atoms with higher energies to target cells that express certain unique biologic characteristics.[5]

MOLYBDENUM-TECHNETIUM SUPPLY CHAIN: THE INTERNATIONAL STANDARD FOR EFFECTIVE LOGISTICS

The most commonly used radionuclide in NM is technetium-99 m (Tc-99 m).[11,12] It is the radioactive decay product of molybdenum 99 (Mo-99) and has a half-life of 6 h. Tc99 m emits 140 keV photons that are efficiently detected with widely available gamma detection technologies.[11] Tc-99 m accounts for about two-thirds of all diagnostic medical isotope procedures in developed such as the USA.[12] Its favorable chemistry allows chemical incorporation into small molecules, ligands, and proteins that concentrate in target organs when introduced into the body.[6] Furthermore, it can be supplied safely and efficiently in the form of molybdenum/technetium generators. Tc-99 m provides relatively low patient doses because it lacks the more harmful alpha or beta radiations and has a short half-life.[5,13]

There are two ways to produce Mo-99 to obtain Tc99 m.[12-16] The more common method occurs in a nuclear reactor by either fission of uranium-235 (U-235) or activation of molybdenum-98 targets. The former is more efficient and considered the "gold standard."[12] The IAEA is accelerating the elimination of the worldwide use of highly enriched uranium (HEU) from medical isotope production in favor of low-enriched uranium (LEU).[12,13] While medical isotope production from LEU targets allays concerns of nuclear proliferation and security, HEU targets contain weapons-grade material and are considered a proliferation hazard for nuclear security.[6,12,13]

After irradiation in a nuclear reactor, the U-235 target is removed and Mo-99 is separated. The target is then packaged and shipped to facilities where Mo-99 m undergoes dissolution. Next, the purified and chemically separated Mo-99 is shipped to facilities for production of technetium generators. The generator is a system that stores Mo-99 and allows Tc-99 m to be recovered for use. It consists of alumina (Al_2O_3) column about the thickness of a pencil.[12] The columns must be prepared in a sterile, radiation shielded, and regulatory-compliant plastic casings that can be delivered by air, ground, or a combination of both to the end users– the hospitals and clinics. Tc-99-generators are only useful for 7–10 days because of the relatively short half-life of Mo-99 (66 h). The Mo-99/Tc99 m supply chain from beginning to the end depends on significant logistics and security arrangements to ensure timely delivery on a weekly or fortnightly basis. Although produced from potentially hazardous sources, the final Mo-99/Tc-99 m product has a small and insignificant potential for malicious use.[5] Furthermore, the public health risk is at its lowest by the time it reaches the end user. Cyclotron production of Mo-99 eliminates the need for HEU targets but is costly and less efficient.[14-16] In nuclear security terms, it is considered favorable as it eliminates the need for the use of reactors and minimizes population risks from reactor accidents.

Any interruption along the supply chain of Mo-99 can have substantial impacts on patient care.[11-17] The international coordination of operational programs between producing organizations has helped to minimize global interruptions in medical isotope production, yet the global supply chain remains vulnerable to disruption.[18,19]

Local supply chain for radionuclide delivery

NM was formally introduced in Nigeria when the IAEA established the first Department of NM at the University College Hospital Ibadan in 2006.[17,20] In 2006, a consensus of medical experts projected that the country would need at least 10 NM centers. A joint project between the Federal Government of Nigeria and the IAEA (NIR6022) was subsequently established to provide two positron emission tomography/computed tomography (PET/CT) scanners and cyclotrons, 18 gamma cameras and overseas training of human resources for NM. The onsite cyclotrons would provide radionuclides for PET/CT while radionuclides for single-photon emission CT (SPECT), SPECT/CT would be imported into the country by air using any of the 7 International Airports in the country.

The Nigeria Nuclear Regulatory Authority (NNRA) enacted by law in 1995 administers radiation safety in accordance with IAEA model regulations.[21] It provides annual import and premise licenses for hospitals receiving radioactive sources for medical use. Logistic companies must also obtain licenses to handle and transport radioactive sources. The Nigeria customs service collects import duties and port charges and must notify the relevant security agencies before dangerous goods are cleared. The operatives of the Nigeria police explosive ordinance disposal (EOD) unit enforce the NNRA act and are authorized to escort radioactive sources including Technetium generators and small packages of radioactive iodine *131-I* during local transit. The chemical, biological radiological and nuclear (CBRN) units of the Nigeria police force, the Nigeria

Security and Civil Defense Corps, Departments of Military Intelligence and state security all provide intelligence support. At inception, executive presidential waiver for the dedicated handling of NM sources provided an efficient radionuclide delivery system. Because the nature of NM radionuclides is poorly understood, radionuclide delivery is vulnerable to frequent setbacks whenever there is a change in leadership in any of the involved organizations at national, state, or local levels. The executive waiver system, therefore, has proved not be sustainable. It is imperative that effective strategies for delivery of radionuclides to the end users are factored in when planning projects for the development of hospital NM services in developing countries.

There have been challenges associated with providing NM services in Nigeria.[17,20,22] The country receives *Technetium generators* and *I-131* majorly from France (Curium) and occasionally from South Africa (NTP). Challenges with importing both radionuclides into the country have included as follows: delays at clearing by customs, delays at clearing and transportation escort by EOD and strike actions by clearing agents. NM services in the country were adversely affected during the global shortage of Mo-99 in 2008/2009.[11] In 2015 a scarcity of foreign exchange induced by low international oil prices halted radionuclide supply for over 6 months at the NM Center in Ibadan. Since 2016, Nigeria's second NM facility located in the capital city, Abuja, has not been able to obtain radionuclides. Such ambiguity of radionuclide delivery is contributory to the low investments in NM in some developing countries which depend on importation for the supply of radioisotopes.[23] With regard to NM investments in developing countries, there have been noteworthy efforts by the IAEA to respond to these needs among member states.[24-26] Through the IAEA many developed countries have provided training and technical support to developing ones. As a result, there is now a long history of collaborations between South Africa and other countries on the African continent for the growth of NM. In recognition, the IAEA achieved significant outcomes in the area of physician training for NM in Nigeria. Whereas Nigeria boasts of 19 NM physicians that have passed the South Africa Fellowship examinations, only four are now gainfully employed. The others are working as medical officers or are underutilized in their former specialties in radiology, radiation oncology, or internal medicine. The lack of recognition for NM as a specialty and the unique need for its independence remains a systemic challenge for the practice in Nigeria. In addition, the absence of health insurance excludes the less wealthy indigent populations from accessing NM care.[22]

THE EVIDENCE FOR SOCIAL ACCOUNTABILITY AND INSIGNIFICANT RISK OF NUCLEAR MEDICINE RADIONUCLIDES

There are nine classes of dangerous goods depending on the nature of the material. Radioactive sources generally fall under class seven dangerous goods.[27] The dangers from class-7 goods result from the emission of ionizing radiation and its attendant risks to humans. Class-7 goods cover a wide range of medical radioactive sources ranging from pacemakers to cobalt sources used in radiotherapy. It also includes radiation sources used in agriculture, oil, and gas industry as well as weapons-grade materials. Such a wide range of ionizing radiation varies according to the type, the physical and chemical form and the activity of the radiation involved. The risks from class-7 goods are further sub-classified according to five categories. Category one sources being potentially most dangerous and category five having the least potential for danger.[28]

These categories provide risk-informed decision making for radiological safety and security.[29] However, it directly applies to sealed sources of radioactivity. Whereas NM involves the use of radionuclides with short half-lives in a source form that is unsealed, the principles of the categorization system may be applied in selected instances involving NM radionuclides.[27] Furthermore, the international code of conduct on the safety and security of radioactive sources prepared by the IAEA exempts individual radioactive sources based on the recognition that their uses are within low activity levels.[3] Individual radionuclides used in NM, though several, are unlikely to be transported at activity levels that will place them in dangerous categories. Therefore, they should not be subject to extreme control.[13] Since the inception of NM in Nigeria, Tc-99 m and I-131, which have half-lives of 6 h and 8 days, respectively, are the only NM radionuclides in use until date. Both radionuclides are relatively cheap and impact the diagnosis and treatment of patients, particularly cancer patients, in Nigeria.[29-32] The IAEA classifies both radionuclides as category 4 on a case-by-case basis.[27] Therefore, Tc-99 m and I-131 are unlikely to be dangerous in the doubtful event of being accessed by terrorists.

There have been no recent acts of warfare involving nuclear weapons since World War II.[28,29,33] However, nuclear power facility accidents have shaped concerns for nuclear terrorism.[20,29] For emphasis, radionuclides used in NM cannot create a nuclear event on the scale of the Chernobyl or Fukushima reactor accidents. The use of low activity short-lived radionuclides as are used in NM may, however, lead to public panic partly related to the overemphasis of risk through the media.[33] Candidate radionuclides that will cause intentional malicious harm by radiation dispersion devices (RDD) include cesium-137, cobalt-60, and strontium-90.[33,34] Although iodine-131 is notoriously famous for its documented public health effects following previous reactor accidents, it is also a weak candidate for harm by RDD.[35] It is also unlikely that sufficient quantities of radioactive iodine will be ordered in one event, further diminishing its utility for an RDD. For example, if 5.5 GBQ of iodine-131 can be given safely to a single patient, how could it course significant toxicity if this same activity dispersed among many victims in a so-called "radiological bomb," especially as its effect on any individual can be reduced by the timely administration of iodine or perchlorate. Fortunately, iodine sufficiency programs in Nigeria have been extremely successful.[36] It has been reported that the risk of developing thyroid cancer in the event of intentional dangerous I-131 exposure is lower in iodine sufficient populations.[37] The risk from spent Mo-99-Tc-99 m generators is also insignificant, at least regarding radiation. In reality, the most dangerous aspect of these generators is their weight and if dropped on a person's foot could cause a foot fracture; hardly a justification for an armed escort. Spent generators may be disposed of by recycling component parts provided that they have been kept under controlled long-term storage.[35]

NUCLEAR MEDICINE AND TERRORISM RISKS IN NIGERIA

The recent upsurge in terrorist incidences in Nigeria has led to increased concerns that terrorists could make dirty bombs if in possession of medical radionuclides.[38] Although terrorist groups have not issued specific threats, these concerns are not unfounded. The term "nuclear" creates undue apprehension in the minds of the public and security agencies.[20,29,37] Furthermore, there have been allegations that government waivers specifically established to allow fast clearing of NM radionuclides have been abused. Given the widespread use of high-activity, potentially harmful radionuclides in other civilian enterprise including food production and engineering, granting special concessions to NM should be carefully considered. Therefore, it is sensible to consider the risk of terrorists acquiring radionuclides as credible, and all efforts must be made to minimize this risk.[38]

From a nuclear security viewpoint, the regulator and security outfits in developing countries have compliance obligations to provide security akin to standards for high-income countries but lack the financial and cultural incentives to do so[38] Furthermore, expansive laws, enacted before the introduction of NM need to be reviewed as aspects of these regulations serve as a disincentive to the use of NM.[21]

Need to reform existing framework for radionuclide safety: The case for nuclear medicine

NM significantly impacts cancer care in the country.[30-32] However, due to a combination of factors, the country still lacks reliable access to NM procedures. Fluctuations in foreign exchange as well as added costs of freight and custom duty charges have a direct impact on the cost of NM procedures. Still, these costs are significantly lower in comparison to NM scans using PET technology. PET radionuclides (Category 5) may be considered a viable alternative to importation of radionuclides. However, production of PET radionuclides involves more complex technology, high initial capital, and significant maintenance costs as well as supporting infrastructure such as stable electricity and human resources for NM.[39]

Current expert opinion is that by 2030, 6 out of 10 NM procedures will be therapy. Lutetium-177 (Lu-177) dotatate peptide receptor radionuclide therapy and Lu-177 prostate-specific membrane antigen (PSMA) for castration-resistant prostate cancer and are now routine procedures in parts of Africa.[8,40,41] The availability of Tc-99-labeled PSMA kits for SPECT imaging and the favorable half-life of Lu-177 holds promise for more accurate diagnosis and highly effective treatment of castrate-resistant prostate cancer than current conventional methods.[42] In the absence of effective radionuclide delivery, Nigeria is already being left behind.[8] The absence of a formal society for NM and the small numbers of NM professionals has not allowed the development of NM at a time when the incidence of cancer and noncommunicable disease (NCDs) is on the rise in Nigeria.[42,43] Fortunately, importing radionuclides require minimal equipment and maintenance.[11,44] Hence, there is a need to optimize the current framework for radionuclide supply in Nigeria.

Recommendations

Strategies to strengthen radionuclide delivery and security are relatively low cost.[11,18,44] Our study urges high priority in the following areas:

Review of existing laws and regulations

A comprehensive review of the Nigeria basic ionizing radiation regulations requires multidisciplinary input, joint deliberations among stakeholders and endorsement of International organizations such as the IAEA and the US Department of Energy. Unlike previous efforts where inputs of NM physicians were excluded, subsequent activities should always include representatives from every professional group in NM. Assistance from non-governmental organizations with similar ideals for securing nuclear and other radioactive materials may be pursued. The regulator and general public must appreciate that radionuclides used in NM by nature carry a small and insignificant risk for nuclear terrorism and therefore require risk appropriate measures. To further ensure nuclear security in Nigeria, the regulatory authority may adopt a policy that favors the importation of only medical isotopes produced from LEU sources. Understanding the local supply chain for radionuclide delivery will circumvent the ambiguity of recent revisions as reflected by current obstacles encountered by NM departments in the country.

Development of communication infrastructure

The Nigeria Atomic Energy Commission, as the coordinating government ministry for nuclear security, can stimulate knowledge production through research projects, seminars and working groups, academia, industry, and professional societies. Knowledge resources for incident response should be published on the websites of cognate stakeholders for public access. We also recommend the use of direct communication lines between the NM professionals and the field agencies. This will enable coordination of radionuclide orders at every step along the supply process. Ideally, security agencies (EOD, CBRN) should be aware of radionuclide delivery ahead of its arrival in the country and understanding that these products are medicinal expedite its transfer through the importation and customs procedures. However, at present, the enabling infrastructure is lacking. International funders may assist by providing information and communications technology equipment designed specifically for this purpose. Although these measures are not fool-proof, they may serve as incentives to increase public confidence and provide the earliest communication to trigger an incidence response.

Provide incentives for nuclear medicine development

Centralized radiopharmacies may serve to consolidate security and monitoring efforts. Although requiring initial set-up costs and unique human resources, it befits the needs of low-and-middle-income countries where resources including trained personnel are limited. Furthermore, it can lead the training, education, and research development of further radiopharmacy capacity. Ultimately, the centralized radiopharmacy encourages participation of the private sector.[23] Mandatory minimum staffing levels for medical physicists at the hospitals and among the security agencies are also recommended. This reflects the critical role of medical physicist in radiation safety at the hospital and their roles in monitoring clearing and transportation of NM sources.[43]

CONCLUSION

The introduction of NM techniques in Nigeria is expected to strengthen the management of cancer and other NCDs. However, ensuring timely delivery of short-lived radionuclides is a determinant of its effectiveness and sustainable growth in Nigeria. NM radionuclides carry a small and insignificant risk for terrorist attacks and thus should receive risk appropriate measures to safeguard nuclear security. NM professionals have a role to play in nuclear security and emergency preparedness response in developing countries where fundamental knowledge about short-lived radioactive sources is limited. It is the strong inter-disciplinary cooperation that is created before a terrorist event that will enable an appropriate incidence response in the unfortunate but unlikely event of a terrorist attack involving NM radionuclides. All stakeholders must, therefore, seek and adopt strategies to enhance radionuclide delivery while strengthening nuclear security.

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